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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1773	

NOTIFICATION DATE	DELIVERY MODE
11/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/804,186	DOETSCH ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This non-final action is in response to the RCE/amendment received on 10/8/10

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-35 provide for the use of the stabilized hydrogen peroxide solution, but, since the claims do not set forth any steps involved in the method, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

3. Claims 14-35 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the method, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

4. Claims 17 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The percent unit in claims 17 and 28 do not specify whether they are in volume or mass. The specification does not clearly recite the unit. Applicant is requested to amend the claims and to show where in the specification the units are disclosed.

Therefore, for purposes of this action, the examiner will presume that the units are in percent by mass.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 14-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimberg et al (US 5,609,821) in view of Feasey et al (US 5,130,053), and further in view of Hilmersson (US 5,569,738).

Regarding claim 14, Grimberg discloses a method for sterilizing packages with a stabilized hydrogen peroxide solution (col.2, lines 55-63 and col.4, lines 3-7), comprising:

(1) The hydrogen peroxide stabilizer is a foodstuff-compatible phosphonic acid (col.3, lines 14-16);

(2) The amount of foodstuff-compatible phosphonic acid stabilizer is less than 50 ppm (col.3, lines 30-32; 1mg/kg = 1ppm); and

(3) The stabilized hydrogen peroxide liquid has a temperature greater than 70^0C (col.3, lines 62-64).

As to the limitation that the liquid is continuously used for at least 16 hours; Grimberg teaches measuring the stability of the stabilized hydrogen peroxide solution for 16 hours at a preferred temperature of 96^0C (col.5, lines 44-46). Grimberg further discloses percent values for the relative losses of stability for the stabilized solutions used in examples 1-4. In Example I, Grimberg teaches that the stabilized hydrogen peroxide solution was used for more than one week (Example 1 in column 4; this is considered as continuous use of greater than 16 hours).

As to the dip bath liquid limitation; Grimberg prefers to apply the sterilizing composition using the spraying approach (col.3, lines 60-62). However, Grimberg does teach using the other conventional liquid dip bath where foodstuff packaging material is

continuously submerged into a heated sterilizing liquid within the bath. It would have been obvious to one of ordinary skill in the art to choose such a dip bath where spraying was not easily employed, such as for a continous film, or for containers having an odd shape, wherein the surfaces were not easily reached by spraying. As such one recognizes that at some time during the operation of the sterilizing bath machine that the heated liquid in the bath has already been continuously used to sterilize the foodstuff packages.

Grimberg fails to teach that the concentration of the stabilizer is from 200 to 500 ppm per liter of the hydrogen peroxide liquid, and also fails to teach the use of a dip bath.

Feasey discloses a sterilizing composition having hydrogen peroxide and phosphonic acid (col.1, lines 5-8, and col.7, lines13-16). Feasey further teaches that the stabilized solution is used in disinfection applications (col.4, line18), and explains that the actual amount of phosphonic acid takes into account several factors, including the extent to which in the future is to be contaminated (col.4, lines 29-35). Feasey goes on to disclose an illustrative sterilization application for sterilizing contact lenses where the concentration of the stabilizing agent is from 50 to 1000 ppm (Example 5 in column 7) since in this concentration range the stabilizer is effective (col.4, lines 29-30) in relation with the concentration of hydrogen peroxide for the stabilized solution to acquire sterilization properties (Example 5).

As to the limitation that the concentration of the stabilizing agent is based on per liter of hydrogen peroxide; Feasey teaches expressing the amount of the stabilizer in

the peroxygen composition (col.4, lines 40-42) where in Example 3 (col.6, lines 31-32), 1000 mg of the stabilizer is present per liter of the hydrogen peroxide solution. Feasey goes on to teach that the manner of expressing concentration depends on the type of application. For example, in acidic conditions concentration is expressed differently than in other conditions (col.4, lines 38-40). Therefore, depending on the intended use one recognizes using alternative units for the concentrations of the stabilizer and the hydrogen peroxide solutions as taught by Feasey.

It would have been obvious to one of ordinary skill in the art at the time of the invention to increase Grimberg stabilizer concentration value to Feasey range from 50 to 1000 ppm since in this concentration range the stabilizer is effective (col.4, lines 29-30) in relation with the concentration of hydrogen peroxide for the stabilized solution to acquire sterilization properties as explained by Feasey (Example 5).

Feasey fails to teach the use of a dip bath.

Hilmersson discloses a method for sterilizing continuously running material web with liquefied hydrogen peroxide (col.1, lines 12-16 and figure 2). Hilmersson further teaches that heated hydrogen peroxide liquid can either be applied through spray nozzles 5 or alternatively through a bath (col.3, lines 39-51) since in both approaches liquefied hydrogen peroxide serves as a sterilization agent for the web (col.3, lines 39-40). Therefore, choosing either approach is considered substituting an art recognized equivalence for the same purpose, i.e., sterilizing web material as explained by Hilmersson (col.3, lines 39-51).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute modified Grimberg spraying approach for Hilmersson dip bath approach since in both methods liquefied hydrogen peroxide serves as a sterilization agent for the web as explained by Hilmersson (col.3, lines 39-40); and choosing either approach is considered substituting an art recognized equivalence for the same purpose, i.e., sterilizing web material as evidenced by Hilmersson.

Regarding claim 24, Grimberg discloses a method for sterilizing packages with a stabilized hydrogen peroxide solution (col.2, lines 55-63 and col.4, lines 3-7), comprising:

(1) The hydrogen peroxide stabilizer is a foodstuff-compatible phosphonic acid (col.3, lines 14-16);

(2) The amount of foodstuff-compatible phosphonic acid stabilizer is less than 50 ppm (col.3, lines 30-32; 1mg/kg = 1ppm); and

(3) The stabilized hydrogen peroxide liquid has a temperature greater than 70^0C (col.3, lines 62-64).

As to the limitation that the liquid is continuously used for at least 16 hours without correcting for hydrogen peroxide stability loss; Grimberg teaches measuring the stability of the stabilized hydrogen peroxide solution for 16 hours at a preferred temperature of 96^0C (col.5, lines 44-46) without any correction to the stability loss. Grimberg further discloses percent values for the relative losses of stability for the stabilized solutions used in examples 1-4. In Example I, Grimberg teaches that the

stabilized hydrogen peroxide solution was used for more than one week (Example 1 in column 4; this is considered as continuous use of greater than 16 hours).

As to the dip bath liquid limitation; Grimberg prefers to apply the sterilizing composition using the spraying approach (col.3, lines 60-62). However, Grimberg does not teach against using the other conventional liquid dip bath where foodstuff packaging material is continuously submerged into a heated sterilizing liquid within the bath. As such one recognizes that at some time during the operation of the sterilizing bath machine that the heated liquid in the bath has already been continuously used to sterilize the foodstuff packages.

Grimberg fails to teach that the concentration of the stabilizer is from 200 to 500 ppm per liter of the hydrogen peroxide liquid, and also fails to teach the use of a dip bath.

Feasey discloses a sterilizing composition having hydrogen peroxide and phosphonic acid (col.1, lines 5-8, and col.7, lines13-16). Feasey further teaches that the stabilized solution is used in disinfection applications (col.4, line18), and explains that the actual amount of phosphonic acid takes into account several factors, including the extent to which in the future is to be contaminated (col.4, lines 29-35). Feasey goes on to disclose an illustrative sterilization application for sterilizing contact lenses where the concentration of the stabilizing agent is from 50 to 1000 ppm (Example 5 in column 7) since in this concentration range the stabilizer is effective (col.4, lines 29-30) in relation with the concentration of hydrogen peroxide for the stabilized solution to acquire sterilization properties (Example 5).

As to the limitation that the concentration of the stabilizing agent is based on per liter of hydrogen peroxide; Feasey teaches expressing the amount of the stabilizer in the peroxygen composition (col.4, lines 40-42) where in Example 3 (col.6, lines 31-32), 1000 mg of the stabilizer is present per liter of the hydrogen peroxide solution. Feasey goes on to teach that the manner of expressing concentration depends on the type of application. For example, in acidic conditions concentration is expressed differently than in other conditions (col.4, lines 38-40). Therefore, depending on the intended use one recognizes using alternative units for the concentrations of the stabilizer and the hydrogen peroxide solutions as taught by Feasey.

It would have been obvious to one of ordinary skill in the art at the time of the invention to increase Grimberg stabilizer concentration value to Feasey range from 50 to 1000 ppm since in this concentration range the stabilizer is effective (col.4, lines 29-30) in relation with the concentration of hydrogen peroxide for the stabilized solution to acquire sterilization properties as explained by Feasey (Example 5).

Feasey fails to teach the use of a dip bath.

Hilmersson discloses a method for sterilizing continuously running material web with liquefied hydrogen peroxide (col.1, lines 12-16 and figure 2). Hilmersson further teaches that heated hydrogen peroxide liquid can either be applied through spray nozzles 5 or alternatively through a bath (col.3, lines 39-51) since in both approaches liquefied hydrogen peroxide serves as a sterilization agent for the web (col.3, lines 39-40). Therefore, choosing either approach is considered substituting an art recognized

equivalence for the same purpose, i.e., sterilizing web material as explained by Hilmersson (col.3, lines 39-51).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute modified Grimberg spraying approach for Hilmersson dip bath approach since in both methods liquefied hydrogen peroxide serves as a sterilization agent for the web as explained by Hilmersson (col.3, lines 39-40); and choosing either approach is considered substituting an art recognized equivalence for the same purpose, i.e., sterilizing web material as evidenced by Hilmersson.

Regarding claims 15 and 25, Grimberg teaches the use of aminotrismethylene phosphonic acid (col.3, lines 14-16).

Regarding claims 16 and 26, Grimberg provides the general teaching that the temperature of the stabilized hydrogen peroxide solution be made greater than 70^0C (col.3, lines 62-64; this teaching is considered to encompass the claimed range). While Grimberg teaches preferred higher temperature values, one of ordinary skill in the art recognizes that some food packaging material may possibly be damaged with a higher preferred temperature of, for example 190^0C. Therefore, modification of this general temperature teaching of Grimberg is considered a matter of optimizing the result-effective variable (temperature of the stabilized solution) that is accomplished, depending on the type of application, through routine experimentation.

Regarding claims 17 and 28, Grimberg teaches that the concentration of hydrogen peroxide in the aqueous solution is between 15% and 70% by weight (col.3,

lines 33-38). The dip bath liquid limitation has previously been addressed in rejecting independent claims 14 and 24.

Regarding claims 18 and 27, Grimberg teaches that the hydrogen peroxide is a hydrogen peroxide distillate (see Examples 1-5 in columns 4-5). The dip bath liquid limitation has previously been addressed in rejecting independent claims 14 and 24.

As to the limitation in claims 34-35 that the concentration of the hydrogen peroxide liquid is foodstuff-compatible; Grimberg teaches (col.4, lines 6-10) that the process using stabilized hydrogen peroxide solution is more particularly suited to the sterilization of packaging material for foodstuff. Therefore, one skilled in the art recognizes that the concentration range values for the liquid hydrogen peroxide taught by Grimberg are foodstuff-compatible.

The dip bath liquid limitation has previously been addressed in rejecting independent claims 14 and 24.

Regarding claims 19-23 and 29-33, Grimberg teaches that hydrogen peroxide stability loss not exceeding 15% (Example 5 in column 5) or not exceeding 12% or not exceeding 11% or not exceeding 2%, or not exceeding 5%.

The limitations regarding the dip bath liquid is continuously used in the method for at least 16 hours have previously been addressed in rejecting independent claims 14 and 24. Also, the temperature limitations for being 85^0C and 70^0C; they have previously been addressed in rejecting independent claims 14 and 24, and also in rejecting dependent claims 16 and 26.

Response to Arguments

9. Applicant's arguments with respect to the newly added claims 14-35 have been considered but are moot in view of the new ground of rejection.

On pages 10-14 of the Remarks/Arguments section; Applicant argues that Grimberg exclusively teaches spraying hot pure stabilized hydrogen peroxide liquid; that Grimberg teaches that using dip bath reduces the stabilizing effects as the liquid hydrogen peroxide over time become more contaminated with packaging material residues where the phosphonic acid stabilizing functions diminishes; that the comparative evidence of record shows that in the absence of the stabilizer, Grimberg teaches pure hydrogen peroxide is more stable; that Applicant's contaminated hydrogen peroxide dip liquid at temperatures higher than the claimed temperature range; and that Grimberg only teaches a concentration of less than 50 mg/kg of phosphonic acid; that reducing the temperature to lower than 96^0C will not significantly affect the pure stabilized hydrogen peroxide of Grimberg.

Grimberg teaches a process of preparing pure stabilized hydrogen peroxide (col.2, lines 9-10). Grimberg does not teach maintaining the purity of the stabilized hydrogen peroxide. Grimberg prefers to use the spraying method, but teaches that alternate methods include using a dip bath and does not teach against using the bath method. The instant rejection shows as evidenced by Hilmersson that choosing either approach is considered substituting an art recognized equivalence for the same purpose, i.e., sterilizing web material as explained by Hilmersson (col.3, lines 39-51).

Grimberg teaches applying hot stabilized hydrogen peroxide in order to form the solution as mist (col.3, lines 66-67) while Grimberg in his generic temperature teaching requires that the temperature of the liquid be greater than 70^0C (col.3, lines 63-64).

Applicants on page 11, first paragraph of the Arguments section cite column and line numbers to provide basis that there is a connection between maintaining a pure liquid and its effect on the function of the stabilizer. However, there are no such teachings or implied guidance to make such a conclusion. The scope of these teachings shows that Grimberg goal is to only prepare a pure stabilized liquid only.

As to the arguments addressing the concentration values for the phosphonic acid in Grimberg; one of ordinary skill in the art would recognize the benefit of increasing the concentration of the stabilizer as suggested by Feasey since Feasey states that the actual amount of the stabilizer takes into account several factors, including the extent to which in the future the composition is to be contaminated (col.4, lines 29-35). The advantage of accounting for the future level of contamination for the stabilized hydrogen peroxide composition will result in preparing stabilized solutions having improved sterilization properties. And this amounts to improving the quality of the stabilized hydrogen peroxide solutions.

The arguments presented on pages 14-18 of the Remarks/Arguments sections have been addressed in the instant new grounds of rejections.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. R. C./
Examiner, Art Unit 1773

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1773